

ATTACHMENT 9 - 510(k) Summary**1. Applicant's Name and Address**

Straumann USA (on behalf of Institut Straumann AG)

Reservoir Place

1601 Trapelo Road

Waltham, MA 02451

Telephone Number: 781-890-0001

Fax Number: 781-890-6464

Contact Person: Linda Jalbert, Director of Regulatory Affairs

2. Name of the Device

Trade Name: ITI Dental Implant System® Monotype Implant

Common Name: Dental Implant

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

ITI One Part Dental Implants (K994104)

TPS Screw

Nobel Biocare Branemark Implants (K993595)

SARGON Dental Implants (K930071)

Implant Innovations Implants (K954347, K960417)

4. Description of the Device

The ITI Monotype implants are self-tapping screw type dental implants made from CP titanium, Grade 4. They are available in various insertion lengths. The implants have the same rough surface as cleared ITI endosseous implants. The transmucosal part has a smooth machined surface to allow for the attachment of epithelial tissue.

5. Intended Use of the Device

The ITI Monotype Dental Implants are intended to be placed in the maxillary and/or mandibular arch to support prosthetic reconstructions in edentulous or partially edentulous patients.

6. Basis for Substantial Equivalence

The modified ITI dental implants are substantially equivalent to ITI Dental Implants, TPS Screw implants, the Nobel Biocare Branemark implants, Sargon and Implant Innovations Dental Implants in intended use, material and design.

The modified ITI dental implants have the same intended use as current ITI dental implants, the Nobel Biocare Branemark implants, and Sargon dental implants.

The modified ITI implants are composed of the same material and have the same surface as the cleared ITI dental implants. In addition, the design of the modified ITI implants is similar to the predicate implants. The implant has a rough surface in contact with bone for osseointegration and a smooth titanium surface in contact with mucosa. The design of the modified implants are also similar to the commercially available Nobel Biocare Branemark and Implant Innovations implants.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Linda Jalbert
Director of Regulatory Affairs
Straumann USA
Reservoir Place
1601 Trapelo Road
Waltham, Massachusetts 02451

Re: K002374
Trade Name: ITI Dental Implant System Monotype Implant
Regulatory Class: III
Product Code: DZE
Dated: August 3, 2000
Received: August 4, 2000

Dear Ms. Jalbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

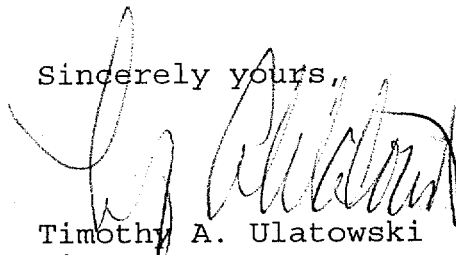
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K002374DEVICE NAME: ITI Monotype Dental Implant

INDICATIONS FOR USE:

ITI Monotype dental implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients.

ITI Monotype dental implants are for use in edentulous jaws in conjunction with a rigidly splinted superstructure on 4 implants. If the implants are rigidly splinted they can be loaded immediately.

ITI Monotype implants can also be used for indications requiring endosseous implants for functional rehabilitation in regions where an ITI two-part implant and an Octa abutment would normally be used.

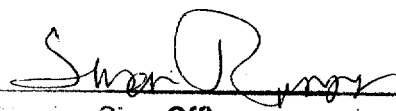
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)



Division Sign-Off
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002374